REMARKS

Claims 1-20 are pending. Applicants elect with traverse Group I (claims 1-6) and SEQ ID NO: 2 for examination on the merits. Applicants reserve the right to prosecute nonelected subject matter in a further patent application.

Notwithstanding the above election, reconsideration of the restriction requirement is requested because examination of all pending claims would not constitute a serious burden. Although the inventions identified by the Examiner are separately patentable, both the need for compact prosecution and the public interest would be served by examination of all claims in a single application. In particular, claims of both Groups I and II should be examined in this application. Thus, claims 7-15 and 18-20 should not be withdrawn from consideration because the polypeptides of Group I and the polynucleotides of Group II are related by structure (i.e., the genetic code relates triplet nucleotides to the amino acids encoded thereby) and function (i.e., both gene and protein confer, at different hierarchies of expression, transferase activity).

In the alternative, Applicants disagree with the allegation in the Action that claims 1-6 lack unity of invention, and therefore belong to different groups of inventions (i.e., either SEQ ID NO: 2 or 4). Traversal is based on claims 1-6 being so linked as to form a single general inventive concept under PCT Rule 13.1. Therefore, Applicants request that the claims of Group I (i.e., claims 1-6) for both SEQ ID NOS: 2 and 4 be examined together in this application. It appears to have been alleged in the Office Action at page 4 that the "sequences have different structure and function." But this is clearly incorrect as a technical matter: SEQ ID NOS: 2 and 4 are both polypeptides (i.e., similar chemical structures) and they are functionally related because they both comprise the amino acid sequences of β1,3-N-acetyl-D-galactosamine transferase proteins. The polynucleotides SEQ ID NOS: 1 and 3 are similar in sequence, and SEQ ID NOS: 2 and 4 represent human and mouse versions of the enzymes.

It is also noted that elected claims 1-3 are generic such that SEQ ID NO: 2 and SEQ ID NO: 4 are linked. Therefore, examination should proceed under the provisions of M.P.E.P. § 809 for both SEQ ID NOS: 2 and 4. The different sequences identified by the Examiner are patentably distinct, but it would not constitute a serious burden for **two**

sequences to be examined in this application because M.P.E.P. § 803.4 refers to the sua sponte waiver of 37 CFR 1.141 et seq. by the Director and his decision to permit a reasonable number of sequences to be examined in a single application ("It has been determined that normally **ten** independent and distinct nucleotide sequences will be examined in a single application without restriction," emphasis added). This decision contradicts and controls ("[The M.P.E.P.] contains instructions to examiners . . . and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application") over the statement at page 5 of the Action that "1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions." Therefore, Applicants submit that both SEQ ID NOS: 2 and 4 should be examined in this application in accordance with the Director's decision and his controlling authority to require examination of more than one sequence in a single application.

Applicants earnestly solicit an early and favorable examination on the merits. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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803.04 * Nucleotide Sequences [R-3]

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the *>Director< may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

>Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode< different proteins are structurally distinct chemical compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the *>Director< has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences,* 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten. In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

See MPEP § 1850 for treatment of claims containing independent and distinct nucleotide sequences in international applications filed under the Patent Cooperation Treaty (PCT) and national stage applications filed under 35 U.S.C. 371.

EXAMPLES OF NUCLEOTIDE SEQUENCE CLAIMS

Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 *et seq.* (and the partial waiver of 37 CFR 1.475 and 1.499 *et seq.*, see MPEP § 1850) include:

(A) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1-1,000;

(B) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000; and

(C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

Applications claiming more than ten individual independent and distinct nucleotide sequences in alternative form, such as set forth in example (A), will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.

Applications claiming only a combination of nucleotide sequences, such as set forth in example (B), will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

Applications containing only composition claims reciting different combinations of individual nucleotide sequences, such as set forth in example

(C), will be subject to a restriction requirement. Applicants will be required to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be examined following the procedures set forth above for example (B). More specifically, the combination will be searched until one nucleotide sequence is found to be allowable with the examiner choosing the order of search to maximize the identification of an allowable sequence. The identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed.

In applications containing all three claims set forth in examples (A)-(C), the Office will require restriction of the application to ten sequences for initial examination purposes. Based upon the finding of allowable sequences, claims limited to the allowable sequences as in example (A), all combinations, such as in examples (B) and (C), containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed.

**>Nonelected claims< requiring any allowable >nucleotide< sequence(s) >should be considered for rejoinder. See MPEP § 821.04<. **

804 Definition of Double Patenting [R-5]

35 U.S.C. 101. Inventions Patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. 121. Divisional Applications.

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that:

> The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

In re Zickendraht, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring). Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982).

Before consideration can be given to the issue of double patenting, two or more patents or applications must have at least one common inventor and/or be either commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement as set forth in 35 U.S.C. 103(c)(2) and (3) pursuant to the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)). Congress recognized that the amendment to 35 U.S.C. 103(c) would result in situations in which there would be double patenting rejections between applications not owned by the same party (see H.R. Rep. No. 108-425, at 5-6 (2003)). For purposes of a double patenting analysis, the application or patent and the subject matter disqualified under 35 U.S.C. 103(c) as amended by the CREATE Act will be treated as if commonly owned. See also MPEP § 804.03. Since the doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis necessarily is on the claims in the multiple patents or patent applications involved in the analysis.

There are generally two types of double patenting rejections. One is the "same invention" type double patenting rejection based on 35 U.S.C. 101 which states in the singular that an inventor "may obtain a patent." The second is the "nonstatutory-type" double patenting rejection based on a judicially created